IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ALCON MANUFACTURING, LTD., ALCON LABORATORIES, INC., and KYOWA HAKKO KOGYO CO. LTD.,	)	Civil Action No. 1:06-cv-1642-RLY-TAB
Plaintiffs,	)	REDACTED
vs.	)	
APOTEX INC. and APOTEX CORP.	)	REDACTED
Defendants.	)	

APOTEX' POST-HEARING MEMORANDUM REGARDING DISCOVERY AND POTENTIAL TRIAL EVIDENCE ISSUES DISCUSSED AT THE COURT'S SEPTEMBER 26, 2008 DISCOVERY HEARING

At the Court's September 26, 2008 hearing concerning discovery and potential trial evidence issues, this Court invited each of the parties to submit a memorandum supporting their positions. In support of their positions, Defendants, Apotex Inc. and Apotex Corp. (collectively "Apotex") state as follows:

I. ALCON SHOULD SUPPLEMENT ITS DOCUMENT PRODUCTION WITH THE INFORMED CONSENT FORMS USED IN TWO ALCON CLINICAL TRIALS BECAUSE THEY ARE RELEVANT TO A PUBLIC USE DEFENSE

The informed consent documents that Apotex seeks from Alcon relate to the public use bar to patentability. Under Section 102(b), a patent claim is not valid if "the invention was… in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States". 35 U.S.C. § 102(b). The test which is now applied by the courts

concerning whether an invention was in public use was set forth in *Pfaff v. Wells*, 525 U.S. 55 (1998). The test articulated in *Pfaff* is whether, prior to the critical date (i.e. one year prior the original filing date of the U.S. application), the claimed invention (i) was publicly used by a person other than the inventor who is under no confidentiality obligation; and (ii) was ready for patenting. Therefore, because the at-issue informed consent documents directly relate to Apotex' public use defense, these documents should be produced.

A. Alcon's clinical testing may be a public use invalidating the at-issue '805 patent

Alcon's testing of the allegedly patented pharmaceutical product on third-party humans may be a public use invalidating the at-issue patent. REDACTED

REDACTED

B. The Informed Consent Forms Should Be Supplemented As Responsive to Apotex' Document Requests

The requested forms are responsive to Apotex' Document Request No. 5 requesting:

All documents concerning any use of the subject matter claimed in the '805 patent on or before the priority date, filing date and/or bar date of the '805 patent, and whether or not you contend such use was not public or was experimental.

Alcon responded to this request by asserting its general objections and stating:

> *Subject to and without waiving the foregoing general and specific objections, Plaintiffs will produce non-privileged documents sufficient to show any use by individuals not employed by Alcon or Kyowa of the subject matter claimed in the '805 patent.*

(Alcon Response to Doc. Req. No. 5).

Because the Informed Consent forms fall within the scope of this request, Alcon previously produced Informed Consent forms for at least five other clinical trials relating to the alleged patented product. REDACTED [redacted] Alcon never specifically objected to producing Informed Consent Forms. Apotex understood from Alcon's discovery responses that all responsive documents would be produced, but later learned in the course of expert discovery that the Informed Consent Forms for these two protocols were not produced.

Contrary to Plaintiffs' argument, Plaintiffs have not produced documents "sufficient to show" the relevant use of olopatadine because they have not produced documents addressing at least one key element of the use: whether the use was public or confidential. It is well settled that "public use under 35 U.S.C. § 102(b) includes any use of the claimed invention by a person other than the inventor *who is under no limitation, restriction or obligation of secrecy to the inventor*." *Netscape Communications Corp. v. Konrad,* 295 F.3d 1315, 1321 (Fed.Cir. 2002)(emphasis added). Section "102(b) erects a bar where, before the critical date, the invention was ready for patenting and was used by a person other than the inventor *who is under no confidentiality obligation*." *Smithkline v. Apotex*, 365 F.3d 1306, 1317 (Fed.Cir. 2004)(vacated on other grounds). Thus, a key inquiry to this case is whether the patients were required to keep the tests confidential. Plaintiffs' refusal to meet their obligation to produce this

properly requested information strongly suggests that the use was not confidential, and thus invalidate the '805 patent.

C. Plaintiffs' citation to *Eli Lilly v. Zenith Goldline* further supports Apotex' position that the subject of patient confidentiality is a highly relevant factor to a public use analysis

Plaintiffs' citation to *Eli Lilly v. Zenith Goldline*, 364 F.Supp. 820, 912 (S.D.Ind. 2005) actually supports the discoverable nature of this information. While the Court ultimately did not find a public use in that case "given the totality of the circumstances," the Court considered and recognized that the patient confidentiality agreements were relevant and should be taken into consideration in the Court's public use analysis at trial. *Id.* ("the presence or absence of a [patient] confidentiality agreement is not controlling. It is simply one of many factors to be taken into to consideration.") The *Eli Lilly* opinion also examined whether the patients were informed of the identity of the drug compound taken. Again, Apotex has identified several patient "informed consent forms" where Alcon did identify the drug compound to the patient. But, neither the Court nor Apotex can know whether the drug compound was identified to the patients involved in these two protocols until the Alcon forms are produced.

Plaintiffs' argument that the protocols did not have a *stated* purpose of treating allergic eye disease is also flawed because it addresses the wrong issue. The relevant issue for Apotex' defense is whether a pubic use of the claimed invention actually occurred in patients. Any stated or unstated purpose of the protocols does not answer the question as to whether an actual public use of claimed invention occurred. The treatment of allergic eye disease and stabilization of conjunctival mast cells are inherent results that flow from applying an olopatadine solution to the

eye. Thus, the public use occurred once the olopatadine solution was applied to human eyes, regardless of the stated purpose of the test.

Plaintiffs' citation to the *Eli Lilly* case is also distinguishable on this point because the patent claim in that case was expressly limited to "an animal, including a human, suffering from or susceptible to schizophrenia." See e.g., U.S. Pat. No. 5,229,382 (cl. 7). Here, the '805 patent claim has no such limitation directed to a human suffering from or being susceptible to allergic eye disease, and thus any public use of olopatadine in human eyes satisfies the public use requirement.

REDACTED

REDACTED

D. Apotex Properly Plead 35 U.S.C. § 102(b) Defense

Plaintiffs' argument that Apotex has not pled that the '805 patent is invalid pursuant to 35 U.S.C. § 102 is inaccurate. Apotex' public use defense arises out of 35 U.S.C. § 102 which states that a patent claim is invalid if "the invention … was in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." In both its First Affirmative Defense and Count I of its Counterclaim for Declaratory Relief, Apotex pled a Section 102 patent invalidity defense as follows:

> The '805 patent is invalid and/or unenforceable on grounds specified in United States Code , Title 35, including failure to comply with one or more of the requirements of 35 U.S.C. § 101, 102, 103 and/or 112.

(Dkt.# 21, pp. 7, 17) Thus, contrary to Plaintiffs' assertions, Apotex properly pled a Section 102 public use defense. The public use defense will be included in Apotex' interrogatory answers once Plaintiffs disclose the documents that contain the remaining elements, namely whether the patients were required to keep the test confidential and whether the patients were told of the specific drug being administered.

The argument by Plaintiffs' counsel, Williams & Connolly, that Apotex' notice pleading lacks too little detail concerning Section 102 is belied by Williams & Connolly's own previous pleadings where it has asserted nearly identical defenses. For example, in *Ethicon Endo-Surgery v. Tyco Healthcare Group LP*, 2006 U.S. Dist. LEXIS 14319 (S.D. Ohio Mar. 9, 2006), the

defendant represented by Williams & Connolly, among others, filed a motion for summary judgment arguing that a prior "public use" of the invention invalidated the patent pursuant to 35 U.S.C. § 102(b). In its Affirmative Defenses and Counterclaim, Williams & Connolly's client asserted Section 102 defenses nearly identical to Apotex' pleading, stating:

> 18. Claim 1 of the 823 patent is invalid for failure to comply with the conditions of patentability set forth in Title 35, United States Code, including, but not limited to, 35 U.S.C. §101, 102, 103, and/or 112.
>
> * * *
>
> 30. Claim 1 of the 823 patent is invalid for failure to satisfy the conditions of patentability set for in 35 U.S.C. § 101, 102, 103 and/or 112.

(Ex. I, pp. 3-4) Thus, Apotex' notice pleading concerning its § 102(b) public use defense is sufficient even under Williams & Connolly's own standards.

E. Plaintiffs' Supplementation of the Informed Consent Forms Will Not Impact the Scheduling Order Because Apotex Does Not Anticipate Expert Reports On The Public Use Defense

REDACTED

The only factual issue that remains in dispute on the pubic use defense appears to be patient confidentiality issue which should be resolved by the production of the informed consent forms themselves. Thus, Apotex does not currently foresee any need for additional expert reports on this public use defense.

Moreover, the later filed *Alcon v. Barr* case is still in fact discovery and will undoubtedly also address this same public use bar defense. Thus, Alcon will be searching for and producing these informed consent forms in the *Alcon v. Barr* case regardless of the outcome of this motion. Apotex submits that it will be more efficient for the Court to now address this public use defense

in the trial here, rather than having to wait for the later *Alcon v. Barr* trial. If the '805 patent is indeed invalided by the Court here, the general public will then have faster access to a generic version of the at-issue drug at a much lower cost than the patented version now sold by Alcon. Thus, it is in the public's strong interest to find out now whether the '805 patent should be invalidated in this case rather than wait for the *Alcon v. Barr* case to adjudicate the same issue. *See, SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1355 (Fed. Cir. 2005)("…there is a stronger public interest in the elimination of invalid patents than in the affirmation of a patent as valid.") REDACTED

II. APOTEX SEEKS DOCUMENTS RELATING TO DR. OHMORI'S WORK ON A KEY PRIOR ART REFERENCE, THE '863 PATENT

Pending before this Court is the instant case and the case *Alcon and Kyowa v. Barr,* Case No. 07-cv-1377-RLY-TAB (S.D.Ind.). The instant case seeks to invalidate the '805 patent only while the *Barr* case seeks to invalidate both the '805 patent and the '863 patent. On July 24, 2008, Barr's attorney sent Plaintiffs' attorney, Williams & Connolly, a letter indicating that Williams & Connolly would soon be producing a large volume of documents, "including documents relating to Dr. Ohmori's work on the '863 patent." (Ex. J). Apotex now seeks a copy of these same documents being produced to Barr, but Plaintiffs have declined to produce any such documents.

Apotex previously requested these same types of documents, but their production was resisted at the time on the basis that the burden of a such a production would outweigh the

potential relevance. See, Alcon letter to Court, Oct. 29, 2008, p. 6 (Ex. K)("The burden that Apotex seeks to impose with this request is tremendous and completely out of line with the potential relevance of the documents. Searching for, gathering, reviewing, and producing such documents would be a huge burden on Plaintiffs and certainly could not be completed between now and when fact discovery is scheduled to close in this case in February of next year. There is no likely benefit on the other side of the scale.")

Because the R&D documents are now being produced to Barr, it will not be at all burdensome for Plaintiffs to make a second copy of its disc containing these documents. At the hearing, Plaintiffs' further conceded there is no burden in producing a second disk.

The relevance of these documents cannot reasonably be disputed. The requested documents are relevant because they likely contain evidence, or could lead to the discovery of admissible evidence, that one of ordinary skill in the art knew or expected that olopatadine would be effective to treat allergic diseases in the eye prior to Plaintiffs' alleged invention. According to the U.S. Supreme Court's most recent discussion on obviousness, the obviousness statute "forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.'" *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007)(quoting 35 U.S.C. §103). Thus, a highly relevant inquiry in determining obviousness is what a person of ordinary skill in the art would have considered obvious prior to or at the time of the invention.

Here, the only relevant difference between the '863 patent and the claims of the '805 patent is the teaching that olopatadine could be used in human eyes, as opposed to the skin, nose or

lungs. However, in light of the pertinent art, it would have been obvious to use olopatadine to also treat allergic eyes, thus the '805 patent is invalid. REDACTED

Contrary to Plaintiffs' argument, Apotex does not seek these research documents solely because the research documents themselves are likely to constitute prior art. Rather, Apotex also seeks these documents because, *inter alia*, Plaintiffs may have discussed and cited to other

[1] AL4943A is the internal Alcon number for olopatadine.

relevant prior art references in their research that are pertinent to the at-issue '805 patent. Thus, discovery of these documents will likely aid the parties in determining the scope and content of the prior art. Determining the scope and content of the prior art is part-one of the four-part test required in any obviousness analysis. Specifically, the following factors must be analyzed in determining whether a patent is invalid due to obviousness: (1) the scope and content of the prior art are determined; (2) the differences between the prior art and the claims are determined; (3) the level of ordinary skill in the art at the time the invention was made is ascertained; and (4) any objective indicia of non-obviousness are examined. *Graham v. John Deere*, 383 U.S. 1 at 17-18 (1966). Because Plaintiffs' argument only addresses part-two of the four-part obvious test, their argument is legally flawed and incomplete.

Finally, contrary to Plaintiffs' argument, the parties did not previously argue or receive a ruling on "this exact issue." Instead, as is clear from the parties' previous letters to this Court, Apotex moved to compel a larger universe of documents when the hearing was held last October 30. At that time, Apotex sought to compel documents, not limited to the '863 prior art patent, concerning "all documents concerning the research and/or development of any medicaments containing olopatadine." Specifically, in its October 29, 2007 letter to this Court, Apotex cited to the following document requests:

> *Apotex Request No. 31:* "All documents and communications concerning the research and/or development of any medicaments containing olopatadine…"
>
> *Apotex Request No. 33:* "All documents comprising or relating to any books, papers, articles, or other publications regarding … topical preparations containing olopatadine…"

> *Apotex Request No. 34:* "All documents that refer or relate to seminars, speeches, presentations, lectures or talks regarding…topical application of medicaments containing olopatadine…"

(Ex. K, Oct. 29, 2007 letter to Magistrate Baker) The requested documents were not limited to documents relating to the '863 patent and that patent was not specifically mentioned in Apotex' letter to the Court. Only after accepting the Plaintiffs' counsel oral representation that a search for these broader requests would involve searches of multiple "warehouses" did this Court find that the burden outweighed the relevance. However, because Alcon can now comply with Apotex' requests by simply making an extra disc, the burden that Alcon previously argued to this Court no longer exists. Apotex respectfully requests that this Court compel Plaintiffs to supplement their discovery by producing to Apotex an extra copy of the disc(s) containing the documents provided to Barr concerning Dr. Ohmori's work relating to the '863 patent. Thus, Apotex seeks a copy of any documents produced to Barr that include "documents relating to Dr. Ohmori's work on the '863 patent."

III. PLAINTIFFS' REQUEST TO STRIKE DEPOSITION EXHIBIT 71 AND ANY RELATED TESTIMONY SHOULD BE DENIED

Plaintiffs' request to strike Exhibit 71 from the record of two depositions and its reference in an expert report should be denied because Exhibit 71 is now part of the deposition record and the inadvertent production provisions of the protective order are no longer applicable. Moreover, even if the Court treats the use of Exhibit 71 as a protective order issue, Plaintiffs' request should be denied because Plaintiffs cannot meet their burden of showing that the attorney-client privilege now applies to Exhibit 71. Any potential claim of privilege was waived when Plaintiffs allowed the un-redacted version of Exhibit 71 to be used and marked as a deposition exhibit, and failed to timely rectify their error. In addition, even if Plaintiffs had not

waived privilege by allowing Exhibit 71 to be used as a deposition exhibit without objection, no privilege could properly be applied to Exhibit 71 under the fraud exception to privilege. The handwritten notations of Alcon's in-house attorneys that appear on Exhibit 71 provide evidence that Plaintiffs knowingly withheld material information and made material misrepresentations to the United States Patent and Trademark Office ("PTO") in order to mislead the patent examiner into issuing U.S. Patent 5,641,805 (the '805 patent")(attached as Ex. N). Accordingly, because these handwritten notations were made to facilitate Plaintiffs' fraud on the PTO, no privilege properly applies to Exhibit 71 under the fraud exception to privilege.

A. Because Exhibit 71 Is Now Part Of The Evidentiary Record, Plaintiffs' Reliance On The Inadvertent Production Provision Of The Protective Order To Seek The Removal Of Exhibit 71 Is Misplaced

Exhibit 71 (attached as Ex. O) was used and marked, without objection, at the January 29, 2008 deposition of Stella Robertson. At that deposition, Ms. Robertson was represented by Daniel Shanahan and Tom Selby, counsel for Plaintiffs. Also present at that deposition was Associate General Counsel for Alcon, Barry Copeland. During Ms. Robertson's deposition, Apotex's counsel introduced Exhibit 71 thereby providing Plaintiffs' counsel with the opportunity to review this document prior to its inclusion into the record. *See* Robertson 1/29/08 Dep. Tr. at 122:20-123:12 (attached as Ex. P). Counsel for Apotex also specifically directed Plaintiffs' counsel to the portion of Exhibit 71 for which they are now asserting privilege, by questioning Ms. Robertson as to whether she recognized the handwritten notations at the top of the document. *Id*. at 123: 5-12. Nevertheless, counsel for Plaintiffs made no objection to the use of Exhibit 71 or to its inclusion as a deposition exhibit. Further, Plaintiffs did not indicate that Exhibit 71 had been inadvertently produced, and did not seek the return of the document during

Ms. Robertson's deposition. In fact, Plaintiffs gave no indication that this was an inadvertently produced document until it was used for a second time at the deposition of Alcon's in-house attorney, Patrick Ryan.

REDACTED

REDACTED Indeed, it was not until a few days after Mr. Ryan's deposition, on February 11, 2008, that Plaintiffs finally sought the return and destruction of Exhibit 71.

As Exhibit 71 is now part of the deposition record and potentially the trial record, Apotex is not obligated under the Protective Order – nor does Apotex have the authority – to unilaterally destroy that exhibit or strike portions of any related deposition testimony. While the protective order in this case contains a provision that allows for the return of inadvertently produced attorney-client privileged communications, it ***does not*** contain a provision that allows for removal of deposition exhibits from the record. Therefore, the use of Exhibit 71 is no longer a protective order issue, but rather, an evidentiary issue which is more properly raised in a motion *in limine* or pursuant to the rules governing deposition practice, Rules 30 and 31 of the Federal Rules of Civil Procedure.

If Plaintiffs intended to seek the return or destruction of this document under the Protective Order, they should have raised this issue when the document was first brought to their attention at the January 29th deposition of Ms. Robertson; or, they should have sought an order pursuant to Federal Rules of Civil Procedure Rule 30. Plaintiffs' other option was to seek to exclude the testimony and exhibit pursuant to Federal Rules of Civil Procedure Rule 32. Plaintiffs' failure to object to the use of Exhibit 71 at Ms. Robertson's deposition resulted in its inclusion into the deposition record. As a result, the Protective Order's provision governing inadvertently produced privileged documents is inapplicable and Plaintiffs can only properly seek to remove this evidence from the record by filing either a motion *in limine* or a motion pursuant to Federal Rules of Civil Procedure Rule 32 with the Court. *See, e.g., Duncan v.*

Fleetwood Motor Homes of Indiana, 2008 WL 2413170, at *1 (N.D. Ind. June 12, 2008) ("A motion *in limine* is a request for guidance by the court regarding an evidentiary question ... a court has the power to exclude evidence *in limine* only when evidence is clearly inadmissible on all potential grounds."). Thus, it was Plaintiffs' burden to bring this issue to the Courts' attention.

Although Plaintiffs complain about the disclosure of Exhibit 71 to Apotex' experts, the document was marked confidential under the Protective Order. Thus, Apotex' experts have and will continue to keep all contents of the document confidential pursuant to a strict Protective Order in this case, and Alcon has suffered no prejudice or harm by the disclosure. Alcon cannot assert the disclosure was a surprise because Apotex notified Plaintiffs that it intended to rely on the deposition exhibit. (Apotex counsel letter, 2/14/08, "to the extent that this document was marked as an original deposition exhibit and remains in the record, we intend to rely on it and will object to any attempt to strike this document, or testimony related thereto, from the record."). REDACTED

REDACTED

B. Plaintiffs Waived Any Potential Claim of Privilege Relating to Exhibit 71 By Allowing It To Be Used As A Deposition Exhibit Without Objection

By allowing Exhibit 71 to be used and marked as a deposition exhibit without objection, and by allowing the privileged handwriting on the top of the document to be used without objection at two separate depositions, Plaintiffs waived any potential claim of privilege they may have had with respect to Exhibit 71. It is well-established that by permitting a document to be used and marked as an exhibit at a deposition, the disclosing party can waive all potential claims of privilege relating to that document. *See, e.g., Federal Deposit Ins. Corp. v. Ernst & Whinney*, 137 F.R.D. 14, 19 (E.D. Tenn. 1991) ("Because the FDIC allowed this document to be produced and marked as an exhibit to depositions, and because no claim of privilege was asserted at the time it was so produced and marked, the undersigned finds that a waiver has occurred to this document"); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co.*, 132 F.R.D. 204, 208-09 (N.D. Ind. 1990) (finding waiver of privilege due to receiving party's "unchallenged use of the letter in the depositions of certain . . . employees"); *Edwards v. Whitaker*, 868 F. Supp. 226, 229 (M.D. Tenn. 1994) (finding waiver where disclosing party did not object to use of disclosed documents in deposition); *Baxter Travenol Labs., Inc. v. Abbott Labs*., 117 F.R.D. 119, 121 (N.D. Ill. 1987) (finding waiver where disclosing party failed to object to use of privileged documents); and *Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp*., 2006 WL 1544621, at *1-2 (W.D. Tex. May 31, 2006) (finding that attorney-client privilege was waived regarding a specific document and related communications, as the attorney failed to object to the use of the

inadvertently produced privileged document during a deposition). Accordingly, by allowing Exhibit 71 to be marked as a deposition exhibit without objection, Plaintiffs waived any claim of privilege they may have had with respect to Exhibit 71.

C. Even If Exhibit 71 Was Inadvertently Produced, Plaintiffs Cannot Meet Their Burden Of Showing That The Attorney-Client Privilege Has Not Been Waived

Plaintiffs now claim that Exhibit 71 was inadvertently produced. When a producing party claims inadvertent disclosure, it has the burden of proving that the disclosure was truly inadvertent and that the attorney/client privilege has not been waived. *Golden Valley Microwave Foods,* 132 F.R.D. at 207. Here, Plaintiffs cannot meet their burden of proving that privilege has not been waived.

In analyzing whether an inadvertent disclosure gives rise to waiver, courts often examine factors such as the "(1) the reasonableness of the precautions taken to prevent inadvertent disclosure; (2) the time taken to rectify the error; (3) the scope of the discovery; (4) the extent of the disclosure; and, (5) the overriding issue of fairness." *Scott v. Clickman*, 199 F.R.D. 174, 178 (E.D.N.C. 2001); *see also*, *FDIC*, 137 F.R.D. at 17. Federal Rule of Evidence 502(b) requires consideration of similar factors. Fed. R. Evid. 502(b) provides:

> "the disclosure does not operate as a waiver in a federal or state proceeding if: (1) the disclosure is inadvertent; (2) the holder of the privilege or protection took reasonable steps to prevent disclosures; and (3) the holder promptly took reasonable steps to rectify the error."

Under the facts of this case, a finding of waiver is warranted under either standard. As discussed above, Plaintiffs allowed Exhibit 71 to be used and included as a deposition exhibit, without objection, at Ms. Robertson's deposition. REDACTED

REDACTED

REDACTED

D. No Privilege Properly Applies To The Handwritten Notations Contained On Deposition Exhibit 71 Under The Fraud Exception To Privilege

Plaintiffs cannot properly claim privilege with respect to Exhibit 71 because the handwritten notes on the document provide evidence that Plaintiffs committed fraud on the United States Patent and Trademark Office (PTO) during the prosecution of the '805 patent.

Plaintiffs committed fraud on the PTO by representing that the compound claimed in their application possessed superior mast cell stabilizing activity as compared with the structurally similar compounds disclosed in U.S. Patent No. 4,923,892 ("the Lever patent")(attached as Ex. R)[2]. The evidence produced in discovery shows that this was a material misrepresentation constituting fraud on the PTO. REDACTED

[2] U.S. Patent No. 4,923,892 was issued to O. William Lever Jr. and was assigned to Burroughs Wellcome and is therefore sometimes referred to as "the Lever patent", "Lever", or "the Wellcome patent."

[redacted]

To invoke the fraud exception to privilege, there must be a *prima facie* showing that the communication at issue was made in furtherance of a fraud. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 807 (Fed. Cir. 2000). In the context of fraud on the PTO, the party challenging the assertion of privilege must make a *prima facie* showing of common law fraud as opposed to inequitable conduct. The elements of common law fraud on the PTO are: a knowing, willful, and intentional act of misrepresentation or omission before the PTO, materiality of the misrepresentation or omission and reliance by the PTO upon the misrepresentation or omission. *W.R. Grace & Co. v. Viskase Corp.*, 1991 WL 150188, at *1 (N.D. Ill. July 30, 1991).

A *prima facie* case of fraud exists when the moving party presents evidence sufficient "to require the adverse party, the one with the superior access to the evidence and in the best position to explain things, to come forward with that explanation." *In re Feldberg*, 862 F.2d 622, 625-626 (7th Cir. 1988)("The question here is not whether the evidence supports a verdict but whether it calls for inquiry."); *United States v. Davis*, 1 F.3d 606, 609 (7th Cir. 1993) ("A party has established a prima facie case whenever it presents evidence sufficient to require the adverse party, the one with superior access to the evidence and in the best position to explain things, to

[3] "BW" presumably refers to Burroughs Wellcome Co., the assignee of the Lever patent, and thus the "BW genus" presumably refers to the family of compounds disclosed in the Lever patent.

come forward with that explanation.").[4] Once there has been a *prima facie* showing of fraud, the privilege is vitiated, unless the party accused of fraud comes forward with a satisfactory explanation. *Id*. As the Supreme Court explained in dictum in *Clark v. U.S.*:

> "There is a privilege protecting communications between attorney and client. The privilege takes flight if the relation is abused. A client who consults an attorney for advice that will serve him in the commission of a fraud will have no help from the law. He must let the truth be told..... To drive the privilege away, there must be 'something to give colour to the charge'; there must be 'prima facie evidence that it has some foundation in fact. When that evidence is supplied, the seal of secrecy is broken."

289 U.S. 1, 15 (1933).

In stressing the difference between the showing necessary to establish inequitable conduct and the showing necessary to show common law fraud, Plaintiffs confuse the burden of proving fraud with the burden of proving that the fraud exception to privilege is applicable to a particularly document. *See* Plaintiffs' September 19, 2008 letter, at pp. 7-8. Plaintiffs lose sight of the fact that "the party seeking to overcome the attorney-client privilege ***need not conclusively prove fraud, or necessarily submit direct evidence*** to make a prima facie showing of fraud..." *Spalding Sports*, 203 F.3d at 808 (emphasis added); s*ee also*, *For Your Ease Only, Inc. v. Calgon Carbon Corp*. 2003 WL 22889442, at *1 (N.D. Ill. December 5, 2003)(the party challenging the assertion of privilege "need not produce direct evidence, nor enough evidence to conclusively prove fraud.").

[4] At the September 26 hearing, Plaintiffs suggested that application of the fraud exception to privilege is governed by Federal Circuit law and that Seventh Circuit law is not applicable. *See* September 26, 2008, Transcript of Hearing on Discovery Matters, at 64: 16-21. However, Plaintiffs have not shown that there is any substantive difference between the standards applied by the Federal Circuit and those of other circuits. In fact, in discussing the fraud exception to privilege, the Federal Circuit has cited case law from other circuits with approval. *See, e.g.,*. *Spalding Sports Worldwide, Inc.*, 203 F.3d at 807 (citing *In re Grand Jury Subpoenas*, 144 F.3d 653, 660 (10th Cir. 1998) ("To invoke the crime-fraud exception, the party opposing the privilege must present prima facie evidence that the allegation of attorney participation in the crime or fraud has ***some foundation in fact***.")(emphasis added).

Here, the evidence adduced during discovery clearly establishes a *prima facie* case of fraud on the PTO sufficient to invoke the fraud exception to privilege with respect to the handwritten notes on deposition exhibit 71. The fact that Plaintiffs have conducted new scientific tests and submitted two new declarations suggests that even Plaintiffs recognize that a *prima facie* case of fraud has been established.

1. Factual Background Relating To Plaintiffs' Fraud On The PTO

The application leading to the '805 patent was not Plaintiffs' first attempt to obtain a patent on the use of olopatadine to treat allergic eye diseases. In October 1993, Alcon first filed patent application Serial No. 08/134,227, entitled "Topical Ophthalmic Formulations for Treating Allergic Eye Diseases." *See* ALP001-003001-3 (attached as Ex. S); Dep. Exhibit 107 (attached as Ex. T); REDACTED The application was assigned to Examiner Fay who rejected each of the 4 claims of the application under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Nos. 4,871,865 and 4,923,892 (collectively "the Lever Patents") in an office action dated December 30, 1993. *See* Dep. Exhibit 109 (attached as Ex. U).

Plaintiffs have admitted that the Lever patents disclose a genus (i.e. family of compounds) that includes olopatadine, the compound claimed in the '805 patent. *See* Excerpts from Dep. Exhibit 4 at ALP001-042092 (attached as Ex. V)("Lever discloses that a genus of tricyclic aromatic compounds (including the Z- and E- isomers recited in Applicants' claims) possess not only antihistaminic activity, but also mast cell stabilizing activity".); *See also* Ex. N

at Col. 1:15-33. The Lever patents also disclose that this genus of compounds is effective for use in the treatment of allergic conditions, including eye diseases such as allergic conjunctivitis. *See, e.g.*, Ex. R, at 5:34-41. The Lever patents further disclose that the compounds of this genus possesses both antihistaminic and mast cell stabilizing properties. *See, e.g.*, Ex. R at col. 5:27-33. Examiner Fay explained that the Lever patents:

> "teach the use of the claimed compounds for the treatment of allergic condition. The above reference also teaches the use of the claimed compounds against allergic conjunctivitis. One skilled in the art would have been motivated to employ the teachings of the above references, since they relate to the use of the claimed compounds for the treatment of different allergic conditions, such as the allergic conditions of the eye. The above references make clear that the use of the claimed compounds for the treatment of allergic condition the eye has been suggested…Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention. Thus one of skilled in the art reading the above references would have been motivated to employ the claimed elements in a manner herein claimed."

Ex. U at ALP001-003032-33.

Accordingly, to overcome the examiner's rejection, Alcon and Kyowa attempted to show that olopatadine was unexpectedly superior to the compounds of the prior art Lever patents through comparative testing. REDACTED

[redacted]

[5] The Lever patent was assigned to Burroughs Wellcome, thus the compounds disclosed in the Lever patent are sometimes referred to as "the Wellcome compounds." "Wellcome compounds I and II" are two of the compounds exemplified in the Lever patents, namely (Z)-11-(3-Dimethylaminopropylidene)-6,11-dihydrobenz[b,e]oxepin-2-carboxylic acid and (Z)-11-(3-Dimethylaminopropylidene)-6,11-dihydrobenz[b,e]oxepin-2-acrylic acid. REDACT [redacted]

[redacted]

[6] KW4679 is the number assigned to olopatadine by Kyowa.

REDACTED

On June 6, 1995, Alcon filed a second patent application directed to the use of the olopatadine to treat ocular allergy. This is the application that eventually became the '805 patent at issue in this suit.[7] REDACTED *Compare* Ex. N at ALP001-001084 with REDACTED However, the data from the testing on *human* conjunctival mast cells is noticeable absent from the file history of the '805 patent.

As originally filed, Claim 1 of the '805 application read: "A method for treating allergic eye diseases comprising topically administering to the eye a composition comprising a therapeutically effective amount of 11-(3-dimethylaminoproplidene)-6,11-dihydrobenz[b,e,]oxepin-2-acetic acid or pharmaceutically acceptable salt thereof." Ex. V, at ALP001-042022. As with the earlier abandoned application, this new application was rejected, *inter alia*, as obvious in light of the prior art, including the prior art Lever patent. In responding to this rejection, Plaintiffs did not dispute the basis for the examiner's rejection, but instead amended the claim to limit it to use in humans and to specify a mechanism of action by which olopatadine treats allergic eye diseases, i.e., stabilization of mast cells. As amended claim 1 reads: "A method for treating allergic eye diseases in humans comprising stabilizing conjunctival mast cells by topically administering to the eye a composition comprising a therapeutically

[7] During the prosecution of this application, Alcon did not disclose the existence of its earlier application directed to the use of olopatadine or that the earlier application had been rejected by the PTO.

effective amount of 11-(3-dimethylaminoproplidene)-6,11-dihydrobenz[b,e,]oxepin-2-acetic acid, or a pharmaceutically acceptable salt thereof." Ex. V, at ALP001-042089. In addition to amending the claim, Alcon presented its arguments in support of patentability. One of the arguments Alcon raised to overcome the examiners' rejection was that olopatadine possessed superior mast cell stabilizing activity compared to the compounds disclosed in the Lever patent. Ex. V, at ALP001-042094. As discussed more fully below, this statement was a material misrepresentation that constituted fraud on the PTO.

2. Plaintiffs' Duty of Candor and Good Faith

The Patent Office faces certain difficulties in view of the limited resources and time available to examine each patent application, as compared to the resources of applicants. Thus, it is clearly important that patent examiner be able to reasonably rely on information provided by the applicant. Moreover, "the public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability." 37 C.F.R § 1.56 (a) (1995). As a consequence, PTO regulations and judicial decisions have imposed special duties on patent applicants and their attorneys, including the duty of candor and good faith. *See Precision Instrument Mfg. Co., et al. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816-18 (1945) (Every patent applicant has an "uncompromising duty" to report to the PTO all facts affecting the patentability of the inventions claimed, to assure that "patent monopolies spring from backgrounds free of fraud or other inequitable conduct.")

The duty of candor and good faith requires disclosure to the examiner of any information which is material to the prosecution of the patent application, and applies not only to the

inventors but also to "every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

3. Plaintiffs Violated Their Duty Of Candor And Good Faith And Committed Fraud On The Patent Office By Affirmatively Misrepresenting The Superior Conjunctival Mast Cell Stabilizing Activity Of Olopatadine Over The Prior Art Compounds And Withholding The 1994 Test Results

One of the ways that Plaintiffs committed fraud on the PTO during the prosecution of the '805 patent was by intentionally misrepresenting that olopatadine possessed superior conjunctival mast cell stabilizing activity compared to the structurally similar compounds disclosed in the prior art Lever patent and by withholding the test data that showed this representation to be untrue.

To overcome the examiner's rejection, Plaintiffs asserted, *inter alia*, that the claims of the '805 patent were not obvious in view of the Lever patent because olopatadine possessed superior mast cell stabilizing activity compared to the compounds disclosed in the Lever patent. *See* Ex. V, at ALP001-042094 ("there is no way to predict, given the disclosures of Kamei et al. and Lever, that the compounds recited in Applicants' Claims would possess significantly superior mast cell stabilization activity compared to the structurally similar compounds exemplified by Lever.")(emphasis added). However, the evidence shows that at the time Plaintiffs made this statement, they were aware that olopatadine did not possess superior mast cell stabilizing activity compared to the compounds disclosed in the Lever patent.

REDACTED

REDACTED

4. REDACTED

REDACTED

Information is material to patentability if there is a "substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991)[8].

[8] Although the PTO amended its rules in 1992 to provide for a different definition of materiality, the Federal Circuit has noted that "the new standard was not intended to constitute a significant substantive break with the previous standard." *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).

Under 37 C.F.R. § 1.56, "information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
> (i) Opposing an argument of unpatentability relied on by the Office, or
> (ii) Asserting an argument of patentability."

37 C.F.R. § 1.56(b) (1995).

In light of the fact that the claims of the '805 patent were rejected as obvious in view of the Lever patent in the prosecution of both the abandoned application and the '805 patent, it is clear that distinguishing olopatadine from the Wellcome compounds was a critical issue in the prosecution of the '805 patent. In addition, it is clear that Plaintiffs were asserting the human conjunctival mast cell stabilizing property of olopatadine as a point of novelty which distinguished the claims of the '805 application from the prior art because Plaintiffs specifically amended their claim to include these limitations in response to the examiner's rejection. *Cf. Litton Systems, Inc. v. Honeywell, Inc.*, 145 F.3 1472, 1475 (Fed. Cir. 1998) ("[W]hen an amendment is made for unknown reasons, the amendment is treated as if it were made for a reason related to patentability.") Thus there can be little question that a reasonable examiner would have consider any information relevant to distinguishing olopatadine from the Wellcome compounds to be particularly important in deciding whether to allow the '805 application to issue as a patent, especially if that information concerned mast cell stabilizing activity.

REDACTED

REDACTED

See 37 C.F.R. § 1.56(b); s*ee also, Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc*., 837 F. Supp. 1444, 1475 (N.D. Ind. 1992), *aff'd*, 11 F.3d 1072 (Fed. Cir. 1993) ("There is a duty to disclose or to even go so far as to 'red flag' contradictory information with regard to test results, where the results appear to be in sharp contrast with what the applicant is telling the Patent Office, since the Patent Office is incapable of verifying comparative tests and has to rely on the candor of the parties submitting those test results").

REDACTED

REDACTED

Plaintiffs' argument that Mr. Ryan's statements regarding the superior mast cell stabilizing activity of olopatadine is not a misrepresentation "because it is true," similarly strains credulity. REDACTED

REDACTED

Plaintiffs' representation to the PTO was that olopatadine "possess significantly superior mast cell stabilization activity compared to the structurally similar compounds exemplified by Lever."); *see* Ex. V, at ALP001-042094 (emphasis added). REDACTED

[9] REDACTED

REDACTED

Plaintiffs' after the fact attempt to reinterpret the misrepresentations they made to the Patent Office should be rejected.

5. The Self-Serving Declaration Of One The Inventors Is Insufficient To Rebut The Evidence That Plaintiffs' Statement Regarding The Superior Mast Cell Stabilizing Activity Of Olopatadine Was A Misrepresentation.

With their letter to the Court, Plaintiffs submitted the Declaration of Dr. Yanni, one of the named inventors of the '805 patent, in an attempt to support their argument that their statement regarding the superior mast cell stabilizing activity of olopatadine was not a misrepresentation. *See* Exhibit 1 to Plaintiffs' September 19, 2008 letter.

As an initial matter, the court should not consider Dr. Yanni's declaration for any purpose. REDACTED

REDACTED

REDACTED

In light of the fact that Dr. Yanni's self-serving statements are contradicted by the documentary evidence, his declaration is insufficient to overcome Apotex's *prima facie* showing of fraud in this case.

6. The Patent Examiner Relied On Plaintiffs' Misrepresentation In Allowing The '805 Patent To Issue.

Plaintiffs clearly submitted their response to the examiner's rejection with the intention that the examiner would rely on it in allowing the '805 patent to issue. In fact, Plaintiffs' response concludes that "Applicants believe that the above amendments ***and remarks*** have placed Claims 1-12 in condition for allowance. Accordingly, allowance of the claims in this application is respectfully requested." Ex. V, at ALP001-042094 (emphasis added). This response overcame the examiners' rejection and the examiner issued a notice of allowance on November 14, 1996. Ex. V, at ALP001-042095-97.

Now that Plaintiffs' misrepresentation has served its purpose, Plaintiffs cannot claim that there is no evidence of reliance. While it is impossible to now go back and examine the thoughts of the examiner at the time he allowed the claims of the '805 patent to issue, the circumstances here show that it was, in fact, Plaintiffs' misrepresentation that finally overcame the examiner's rejection.

As is evidenced by their amendment, it is the human conjunctival mast cell stabilizing property of olopatadine that Plaintiffs asserted as a point of novelty of the '805 patent. However, because the prior art Lever patent already disclosed that this family of compounds had mast cell stabilizing properties and that they could be used to treat ocular allergy in humans, it was necessary for Plaintiffs to show that olopatadine showed unexpected superiority over these prior art compounds to overcome the Examiner's rejection. Therefore, Plaintiffs' representation that olopatadine possessed superior mast cell stabilizing activity compared to the Wellcome compounds was a critical issue during the prosecution of the '805 patent.

Plaintiffs' assertion that there were alternative arguments given in the remarks[10] and that the examiner may have instead relied on those arguments in allowing the '805 patent ignores the fact that without a showing that olopatadine was superior to the Wellcome compounds, Plaintiffs would not have been able to overcome the examiner's rejection.

REDACTED

As stated in *Manville Sales v. Paramount Systems, Inc.*,

> No one can tell with certainty what would have happened if the applicant had dealt fairly and openly with the Patent Office. But the fact remains that the applicant did withhold relevant facts. Which side in this litigation is to sustain a detriment from the contract? It is appropriate that it be Manville who sustains it. Any other rule would fail adequately to discourage conduct of this sort merely because of the circumstance, which must be present in many cases, that it turns out to be impracticable to ascertain what the Examiner, who did not know the true facts, would have done if he had known them.

[10] Many of the other arguments raised by Plaintiff in its response to the examiners rejections also constitute material misrepresentations. REDACTED

1987 WL 16888, at *5 (E.D. Pa. September 11, 1987). Thus, while the evidence shows that the examiner relied on the misrepresentation, to the extent that there is any ambiguity as to the examiner's reliance, this issue should be decided in Apotex favor.

7. Consideration Of The Totality Of The Circumstances Warrants A Finding That Plaintiffs Intended To Deceive The Patent Office Into Issuing The '805 Patent.

In the sophisticated world of patent prosecution, guilty applicants rarely leave "smoking gun" evidence of their deceptive intent. In fact, "[d]irect proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." *LaBounty Manufacturing, Inc. v. United States International Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) ("Intent need not be proven by direct evidence and it is most often proven by a showing of acts the natural consequences of which are presumably intended by the actor.")(internal quotations omitted); *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 2007 U.S. App. LEXIS 11606, at *2-3 (Fed. Cir. 2007) ("With regard to the issue of intent, the law recognizes that deceptive intent is virtually never shown or disproved by direct evidence. Instead, the ultimate fact finding on the issue depends on assessment of all the inferences, favorable and unfavorable, that can be drawn from pertinent evidence.").

The facts and circumstances in this case are more than sufficient to support a *prima facie* case that Plaintiffs intended to deceive the patent office by knowingly misrepresenting the superior mast cell stabilizing activity of olopatadine over the prior art compounds of Lever [redacted]

There can be no doubt that Plaintiffs were aware of the significance of the prior art Lever patents and that these patents were a barrier to obtaining a patent on the use of olopatadine to

treat allergic eye diseases. REDACTED [redacted] Plaintiffs' claim to the use of olopatadine to treat allergic eye diseases was again rejected as obvious in light of the Lever patent during the prosecution of the '805 patent. In light of these multiple rejections, Plaintiffs knew that any comparative testing of olopatadine with the compounds of the Lever patent would be material to the prosecution of the '805 patent. REDACTED [redacted] *See* *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) ("intent to deceive may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application."); s*ee also, Cargill, Inc. v. Canbara Foods, Ltd*, 476 F.3d 1359, 1366 (Fed. Cir. 2007)("The repeated nature of that rejection demonstrates that the applicant should have been aware of the materiality of the omitted test data, and, therefore, the district court properly considered it as

significant circumstantial evidence of an intent to deceive the PTO about the evidence relevant to the application.").

Plaintiffs' intent to deceive is not only evidenced by the fact that they intentionally withheld material information from the PTO, but also from the fact that Plaintiffs knowingly and affirmatively misrepresented that olopatadine possesses superior mast cell stabilizing activity. *Norton v. Curtiss*, 433 F.2d 779, 796-7 (C.C.P.A. 1970) ("Under ordinary circumstances, the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent."). REDACTED [redacted] *See LaBounty Mfg.*, 958 F.2d at 1076 (ruling that inference of deceptive intent was supported by evidence of applicant making patentability arguments that could not have been made had the withheld prior art been disclosed); *see also, GFI, Inc., v. Franklin Corp.*, 265 F.3d 1268, 1274-75 (Fed. Cir. 2001).

REDACTED [redacted] In fact several of the arguments made in response to the examiners' rejection were dependant upon material misrepresentations and/or omissions of material information. REDACTED [redacted] Plaintiffs' pattern of misconduct during the prosecution of the '805 patent further supports a finding that Plaintiffs intended to deceive the Patent Office into allowing the

'805 patent to issue. *Paragon podiatry Laboratory Inc. v. KLM Labs., Inc*, 984 F.2d 1182, 1193 (Fed. Cir. 1993) ("The prosecution of the patent application in this case, viewed in its entirety, demonstrates an overriding pattern of misconduct sufficient to support the district court's finding of culpable intent."). REDACTED

8. The Self-Serving Declaration Of The Attorney Responsible For Prosecuting The '805 Patent Is Insufficient To Overcome The Evidence Of Plaintiffs' Deceptive Intent

Plaintiffs have also submitted the declaration of Mr. Ryan, the attorney who prosecuted the '805 patent as evidence of Plaintiffs' subjective intent. *See* Exhibit 3 to Plaintiffs' September 19, 2008 Letter. As with the Yanni Declaration, the Court should not consider Mr. Ryan's declaration for any purpose. Apotex has not been able to explore the statements contained in Mr. Ryan's declaration because it was created after his deposition and after the close of fact discovery. In addition, through this declaration, Plaintiffs are using the testimony of one of their attorneys as a sword to rebut the evidence of deceptive intent, while at the same time they are relying on the attorney client privilege as a shield to withhold the documentary evidence that would allow Apotex to fully explore the issue of intent. To the extent that Plaintiffs rely on Mr. Ryan's statements as evidence of intent, Plaintiffs have waived their claim of privilege with respect to any documents relating to the Lever patent or the compounds disclosed therein that was authored or received by Mr. Ryan. Accordingly, Apotex respectfully requests the Court

compel Plaintiffs to produce any such documents previously withheld on the grounds of privilege.

Even if considered, Mr. Ryan's declaration cannot overcome the evidence of Plaintiffs' deceptive intent because it merely contains self-serving statements that are inconsistent with the documentary evidence.

REDACTED

REDACTED

Mr. Ryan's uncorroborated denials are simply insufficient to rebut the strong evidence of deceptive intent in this case. *See Critikon*, 120 F.3d at 1257; *See also, General Electric Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994) ("[M]ere denials of

[1] REDACT

intent to mislead may not be sufficient to overcome circumstantial evidence of intent to deceive...").

9. No Privilege Properly Applies To Deposition Exhibit 71 Because This Communication Was Made In Furtherance Of Plaintiffs' Fraud On The PTO

The evidence presented in the above discussion clearly establishes a *prima facie* case of fraud on the PTO sufficient to invoke the fraud exception to Privilege. The evidence shows that Plaintiffs made a deliberate decision to withhold material information from the PTO, thereby allowing them to make material misrepresentations and deceive the examiner into allowing the '805 patent to issue. REDACTED

REDACTED

However, in making this argument Plaintiffs ignore the fact that their fraud began as early as 1993 when the examiner's relied on the Lever patents to reject Plaintiffs' first application for a patent on the use of olopatadine to treat ocular allergy. REDACTED

The misrepresentation Mr. Ryan made to the PTO in 1996 merely consummated a fraud that began much earlier.

REDACTED

Accordingly, no privilege applies to Exhibit 71 under the

fraud exception to privilege and the Court should deny Plaintiffs' request to strike Exhibit 71 from the record of two depositions and its reference in an expert report.

Dated: October 16, 2008

Respectfully submitted,

APOTEX INC. and APOTEX CORP.

s/Joseph E. Cwik
Joseph E. Cwik
Michael A. Krol
HUSCH BLACKWELL SANDERS WELSH & KATZ
120 South Riverside Plaza — 22nd Floor
Chicago, Illinois 60606
Telephone: (312) 655-1500
Facsimile: (312) 655-1501
joseph.cwik@huschblackwell.com
michael.krol@huschblackwell.com

Robert B. Breisblatt
Craig M. Kuchii
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe Street
Chicago, IL 60661-3693
Telephone: (312) 902-5480
Facsimile: (312) 577-8792
Robert.Breisblatt@kattenlaw.com
Craig.Kuchii@kattenlaw.com

Gayle A. Reindl
Abram B. Gregory
TAFT STETTINIUS & HOLLISTER LLP
One Indiana Square, Suite 3500
Indianapolis, Indiana 46204-2023
Telephone: (317) 713-3500
Facsimile: (317) 713-3699
greindl@taftlaw.com
agregory@taftlaw.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing APOTEX' POST-HEARING MEMORANDUM REGARDING DISCOVERY AND POTENTIAL TRIAL EVIDENCE ISSUES DISCUSSED AT THE COURT'S SEPTEMBER 26, 2008 DISCOVERY HEARING was served on this the 16th day of October, 2008 upon the attorneys for the Plaintiffs as follows:

VIA FED EX
Adam L. Perlman
Bruce Roger Genderson
Daniel P. Shanahan
Jessamyn S. Berniker
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
(202) 434-5000
Fax: (202) 434-5029
aperlman@wc.com
bgenderson@wc.com
dshanahan@wc.com
jberniker@wc.com

VIA HAND DELIVERY
Deborah Pollack-Milgate
Donald E. Knebel
Paul B. Hunt
BARNES & THORNBURG LLP
11 S. Meridian Street
Indianapolis, IN 46204-3535
(317) 236-1313
Fax: (317) 231-7433
dmilgate@btlaw.com
dknebel@btlaw.com
phunt@btlaw.com

s/Gayle A. Reindl
Gayle A. Reindl
TAFT STETTINIUS & HOLLISTER LLP
One Indiana Square, Suite 3500
Indianapolis, Indiana 46204-2023
Telephone: (317) 713-3500
Facsimile: (317) 713-3699
greindl@taftlaw.com